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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,977	06/14/2007	Mark Ashby	1001.2219102	1136

28075 7590 10/17/2008
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EXAMINER	
MASHACK, MARK F	
ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
10/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,977	ASHBY ET AL.	
	Examiner	Art Unit	
	MARK MASHACK	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,27,40-49, 59 and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,27,40-49,59 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/28/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. **Claims 29-33** are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/25/2008.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 40-42, 44-49, 59-60** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash et al. (US 5,700,277)** in view of **Hannam et al. (US 5,649,959)**.

Regarding Claim 1 and 40, Nash et al. disclose an apparatus to intervascularly promote hemostasis at a blood vessel puncture site comprising:

a flexible plug or disk **32** having a center, a top surface, and a bottom surface, the plug or disk **32** is capable of circumferentially covering the blood vessel puncture sight depending on the size of the puncture sight (FIG 4-6);

a release mechanism (severance of proximal end of suture **34**; (Column 8, Lines 28-33) including a hemostatic material or body **30** coupled to the center of the flexible plug and a resilient extension member or connector **36** coupled to the hemostatic material opposite the flexible plug, the release mechanism positioning and releasing the flexible plug intervascularly at the blood vessel puncture site (FIG 9 and Abstract)

Nash et al. is silent on the flexibility of the disk for it to conform to the inner wall of the vessel.

However, **Hannam et al.** teaches of a plug **30** that is sufficiently rigid to prevent the plug from passing through the puncture but sufficiently flexible to conform generally to the shape of the interior of the artery (Column 7, Lines 25-40).

All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Hannam et al.**, it would have been obvious to one of ordinary skill in the art at the time invention to modify the disk of **Nash et al.** by making it flexible enough to conform to the

inner wall of the vessel. Doing so would reduce the potential of injuring the arterial tissue (Column 7, Lines 25-40).

Regarding Claim 41, Nash et al. disclose the connector **36** has a smaller diameter than a flexible disk diameter and a hemostatic body diameter **30** (FIG 1-3).

Regarding Claim 42, Nash et al. disclose a release mechanism coupled to the hemostatic body (severance of proximal end of suture **34**; Column 8, Lines 28-33).

Regarding Claim 44 and 59, Nash et al. disclose the release mechanism comprises a resilient extension member **52** coupled to the center of the hemostatic body, the resilient extension member **52** having an aperture **56** at a top (Column 6, Lines 35-55, and FIG 1-3).

Regarding Claim 45 and 60, Nash et al. disclose a suture **34** looped through the aperture **56** (FIG 1-3).

Regarding Claims 46 and 48, Nash et al. disclose all of the claimed limitations except for the resilient extension member being made of a hemostatic material. **Nash et al.** actually teach away from the resilient extension member being made of a hemostatic material (Column 2, Lines 7-8; resilient extension member **52** is integral with the plug **32**).

However, **Hannam et al.** teach of a plug **32** and resilient extension member **68** being made of a hemostatic material (Column 7, Lines 41-54).

Nash et al. discloses the claimed invention except for the resilient extension member being made of a resilient, hemostatic material. Given the teachings of **Hannam**

et al., it would have been obvious to one having ordinary skill in the art at the time of the invention was made of a hemostatic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Doing so would provide a resilient temporary seal that would be absorbed within the body after a relatively short period of time (Column 7, Lines 41-54).

Regarding Claim 47 and 49, Nash et al. disclose all of the claimed libations except for encapsulating the resilient extension member with a biocompatible dissolvable capsule.

However, **Hannam et al.** teach of introducing gelatinous material such as a fibrin glue proximal the anchor (Column 4, Lines 38-57).

All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Hannam et al.**, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the resilient extension member with a biocompatible dissolvable capsule. Doing so would retain the anchor in the vessel (Column 4, Lines 38-57).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 27** rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash et al.** in view of **Hannam et al.** as applied to claim 1 above, and further in view of **Haaga (US 5,254,105)**.

Regarding Claim 27, Nash et al. disclose all of the claimed limitations except for the hemostatic material being encapsulated in a biocompatible dissolvable capsule.

However, **Haaga** teaches of vascular surgical device comprising a hemostatic material being encapsulated in a biocompatible dissolvable capsule (Column 1, Line 59, - Column 2, Line 8).

All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Haaaga**, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the hemostatic material by encapsulating it in foam. Doing so would provide a time-release mechanism to enhance the clot formation (Column 1, Lines 67, - Column 2, Line 5).

7. **Claims 43** rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash et al.** in view of **Hannam et al.** as applied to claim 1 above, and further in view of **Houser et al. (US 6,726,696)**.

Regarding Claim 43, Nash et al. disclose the release mechanism is a suture having a first end secured to the hemostatic body with a knot. **Nash et al.** does not disclose the attachment of the suture to the hemostatic body by an adhesive.

However, **Houser et al.** teach of the securement of a patch to a deployment device with an adhesive (Column 2, Lines 28-32).

Given the teachings of **Houser et al.**, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute one known element of adhesive for another element of a knot to yield predictable results. Doing so would secure the hemostatic body to the release mechanism.

Response to Arguments

8. **Regarding Nash's anticipation of Claims 1, 40-42, and 44-45**, applicant's arguments have been considered, but are moot in view of the new ground(s) of rejection.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

//Mark Mashack/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773